HFI 35 (purged)

DEPARTMENT OF HEALTH & HUMAN SERVICES **PUBLIC HEALTH SERVICE**

D1268 B

Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P. O. Box 25087
Denver, Colorado 80225
TELEPHONE: 303-236-3000

March 18, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Geoff Swett, Acting President
Fresinius Medical Care, North America
2 Ledgemont Center
95 Hayden Avenue
Lexington, MA 02173

PURGED

Ref. # - DEN-97-14

Dear Mr. Swett:

During an inspection of your firm, NMC Homecare, Inc., 7032 South Revere Parkway, Suite 300, Englewood, Colorado, on February 13-26, 1997, Consumer Safety Officer Audrey Vigil determined that your firm transfills Liquid Medical Oxygen U.S.P. and fills Compressed Medical Oxygen U.S.P. to patient home units. Medical Oxygen is a drug product as defined by section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated inspection revealed that your product, Oxygen U.S.P., is adulterated under section 502(a)(2)(B) of the Act in that the controls used for the manufacturing, processing, packing, or holding of this product are not in conformance with current good manufacturing practice regulations (GMPs) under Title 21, Code of Federal Regulations (21 CFR), parts 210 and 211. Deviations noted during the inspection included, but were not limited to the following:

1. Failure to test each lot of incoming bulk oxygen to determine conformance with appropriate specifications for identity and strength [21 CFR 211.84(d)(2)]. For example, a valid Certificate of Analysis was not obtained for the bulk liquid oxygen which was subsequently distributed during January and February 1997, nor was other testing performed by your firm.

2. Failure to provide adequate documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished and reviewed [21 CFR 211.188(b)]. For example, there are no records covering the processing of Medical Oxygen from January through November 1996.

3. Failure to follow written procedures designed to assure that Oxygen U.S.P., which is transferred into home units, has the identity and strength it is purported to or represented to possess [21 CFR 211.100(a)]. For example, written procedures were not followed during January and February 1997 in that no manufacturing records were maintained for processing Medical Oxygen.

4. Failure to provide training sufficient to enable employees to perform their assigned functions [21 CFR 211.25(a)]. For example, much of the documentation of manufacturing steps, testing procedures and results, and the delivery of Medical Oxygen is inadequate or missing from January 1993 through February 1997.

5. Failure to properly calibrate the analyzer used for the assay of Liquid Oxygen U.S.P. [21 CFR 211.160 (b)(4)]. For example, there is no evidence indicating that such calibration took place prior to November 4, 1996.

6. Failure to maintain records of the periodic calibration of laboratory instruments, apparatus, gauges and recording devices [21 CFR 211.194(d)]. For example, the Weekly Liquid Oxygen Scale Calibration and the Field Oxygen Analyzer Calibration Logs have not been maintained prior to February 13, 1997, and November 4, 1996, respectively.

7. Failure to establish adequate written procedures for the receiving of complaints [21 CFR 211.198].

8. Failure to perform and document adequate pre-fill operations on each medical oxygen cylinder, prior to filling [21 CFR 211.84(d)(3)]. For example, there are no procedures nor records which show that the external vessel, valve, volume or contents gauge, or product label are inspected prior to filling.

9. Failure to establish written procedures for the reconciliation of the quantities of labeling issued, used, and returned. [21 CFR 211.125(c)].

At the conclusion of this inspection, Consumer Safety Officer Vigil issued a written report of observations (FDA 483) to Ms. Monica Seay, General Manager. A copy of that report is enclosed for your reference.

The above identification of violations is not intended to be an all inclusive list of deficiencies at your facility. As President, it is your responsibility to assure adherence with all requirements of the Act and Good Manufacturing Regulations.

These deviations may be indicative of corporate wide non-compliance. We recommend that internal audits be conducted at all your medical gas facilities and appropriate action be taken to assure that similar violations are not occurring at other locations.

By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection of your firm revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

I am enclosing a copy of the Food and Drug Administration's booklet entitled Compressed Medical Gases Guideline; a copy of the Federal Food, Drug, and Cosmetic Act; a copy of the Fresh Air '96 speech by Mr. Duane Sylvia of FDA's Center for Drug Evaluation and Research; and 21 CFR 211. The Compressed Medical Gases Guideline contains useful information on how to comply with the requirements of 21 CFR 211.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action, including seizure or injunction, without further notice. Federal agencies are advised of the issuance of all warning letters so that they may take this information into account when considering the award of contracts.

We acknowledge that we have received your letter of March 5, 1997. We currently have the response under review, and will advise you in a separate letter if we have any concerns with your response.

Please advise this office in writing, within fifteen (15) working days after receipt of this letter, of the specific actions you have taken to correct the violations. Your response should include: (1) each step that has or will be taken to completely correct the current violations and prevent the recurrence of similar violations; (2) the time when correction will be completed; (3) any reason why the corrective action is not completed within the response time and (4) any documentation necessary to indicate correction has been achieved. Your response should be directed to Ms. Shelly L. Maifarth, Compliance Officer, at the above address.

Sincerely,

Gary C. Dean

Gary C. Dean
District Director

Enclosures
As Stated in Letter

cc: Monica Seay, General Manager
NMC Homecare, Inc
7032 S. Revere Parkway, Suite 300
Englewood, Colorado 80112

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